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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/884,859

06/18/2001

Hugh R. Sharkey

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3139

21971

7590

09/12/2002

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EXAMINER

SCHOPFER, KENNETH G

ART UNIT

PAPER NUMBER

3739

DATE MAILED: 09/12/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

S.M.

Office Action Summary

Application No.

09/884,859

Applicant(s)

SHARKEY ET AL.

Examiner

Kenneth G Schopfer

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 June 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 53-73 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 53-73 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Claim Objections

1. The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claims 52-72 have been renumbered 53-73. The preliminary amendment to the present case cancelled claims 1-52 and added claims 52-72. The new claims have been renumbered 53-73.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 53-73 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sharkey et al. (USPN 6007570) in view of Leschinsky et al. (USPN 5871501).

4. Referring to claims 53, 59-65, and 68, Sharkey et al. teach all of the limitations of these claims as described above except for the method including the steps of extending a guide wire from a distal end of the introducer into an intervertebral disk, attaching the guide wire to an inner wall of the disc, and advancing a probe along the guide wire into the intervertebral disc. Sharkey et al. do teach a method for treating an intervertebral disc including the steps of delivering an

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introducer into or adjacent an intervertebral disc, advancing a probe through the introducer and into the intervertebral disc, and performing a function within the disc after the probe is advanced. The probe includes a functional element that may be a monopolar or bipolar radiofrequency energy delivery device (column 17, lines 32-44) or a resistive heating mechanism (column 17, lines 9-20). Further, the probe includes a lumen for delivering and aspirating material in the disc (column 15, lines 30-45).

Leschinsky et al. teach a guide wire that is extended through an introducer and can be attached to a wall of tissue. (figures 6 and 7). It would have been obvious to one of ordinary skill in the art at the time of invention to use a guide wire as in Leschinsky et al. in the method of using the device of Sharkey et al. in order to provide an effective means for accurately guiding the probe to a treatment site within an intervertebral disc.

5. Referring to claim 54 and 55, the combined device of Sharkey et al. and Leschinsky et al. teaches all of the limitations of this claim as described above except for the method step of inserting or hooking a distal portion of the guide wire into the inner wall of the disc. It would have been obvious to one of ordinary skill in the art at the time of invention that a suitable means for attaching the guide wire to the inner wall of the disc when using the combined device of Sharkey et al. and Leschinsky et al. would be to insert or hook the distal portion of the guide wire into the distal wall similar to the attachment shown in the figures of Leschinsky et al.

6. Referring to claim 56, the combined device of Sharkey et al. and Leschinsky et al. teaches all of the limitations of this claim as described above except for the method step of inserting a retractable hook on the distal end of the guide wire into the inner wall of the disc.

The cross locking of the guide wire of Leschinsky et al. (figures 2, 6, and 7) may be described as

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a retractable hook. Thus, it would have been obvious to one of ordinary skill in the art at the time of invention that the retractable hooking mechanism of Leschinsky et al. in the combined device of Sharkey et al. and Leschinsky et al. could have been inserted into the inner wall of the disc to effectively attach the guide wire to the wall.

7. Referring to claim 57, the combined device of Sharkey et al. and Leschinsky et al. teaches all of the limitations of this claim as described above except for the method step of hooking multiple hooks on the distal end of the guide wire into the inner wall. It would have been obvious to one of ordinary skill in the art at the time of invention to include multiple hooks on the guide wire of the combined device of Sharkey et al. and Leschinsky et al. in order to provide an even more effective means of attaching the guide wire to the inner wall of the disc.

8. Referring to claims 58 and 69, the combined device of Sharkey et al. and Leschinsky et al. teaches all of the limitations of this claim as described above except for the method step of extending the guide wire with sufficient force to advance it through the nucleus pulposus and sufficient flexibility to be compliant with an inner wall of the annulus fibrosus without puncturing the annulus fibrosus. Sharkey et al. teach that the probe should be advanced with sufficient force to advance it through the nucleus pulposus and around the wall of the annulus fibrosus without puncturing the annulus fibrosus (column 6, lines 41-51). It would have been obvious to one of ordinary skill in the art at the time of invention that the guide wire in the combined device of Sharkey et al. and Leschinsky et al. would be advanced in a manner similar to the probe of Sharkey et al. as stated above in order to ensure that the annulus fibrosus was not further damaged.

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9. Referring to claims 66 and 71, the combined device of Sharkey et al. and Leschinsky et al. teaches all of the limitations of this claim as described above. Further, Leschinsky et al. teach that the guide wire has a proximal portion 82 that acts as a handle and a control element for actively steering the guide wire.

10. Referring to claim 67, Sharkey et al. and Leschinsky et al. teach all of the limitations of this claim as described above except for the RF electrodes comprising a plurality of alternating one or more active and return electrodes which are positioned on the probe such that pairs of active band and return band electrodes are adjacent each other. Sharkey et al. do teach a bipolar RF electrode functional element 18 and a metallic band electrode. It would have been obvious to one of ordinary skill in the art at the time of invention to include active and return band electrodes adjacent each other in the combined device of Sharkey et al. and Leschinsky et al. in order to create an effective bipolar functional element on the distal end of the probe.

11. Referring to claim 70, the combined device of Sharkey et al. and Leschinsky et al. teaches all of the limitations of this claim as described above. Further, the guide wire of Leschinsky et al. does taper to a smaller diameter toward the distal end.

12. Referring to claim 72, Sharkey et al. and Leschinsky et al. teach all of the limitations of this claim as described above except for a portion of the guide wire being radiographically visible. Sharkey et al. teach that the probe should include radiographically opaque portions so that the advancement of the probe can be easily tracked. It would have been obvious to one of ordinary skill in the art at the time of invention to also include radiographically visible portions on the guide wire of the combined device of Sharkey et al. and Leschinsky et al. in order to track the insertion of the guide wire.

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13. Referring to claim 73, Sharkey et al. and Leschinsky et al. teach all of the limitations of this claim as described above except for the distal portion of the guide wire having one or more flat sides. It would have been obvious to one of ordinary skill in the art at the time of invention that the use of flat sides on the guide wire as in the claims represents an unpatentable design choice over the distal end of the guide wire of the combined device of Sharkey et al. and Leschinsky et al. that would not change the functionality of the device.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kenneth G Schopfer whose telephone number is 703-305-2649.

The examiner can normally be reached on M-F (8:00-5:30) First Friday Off.

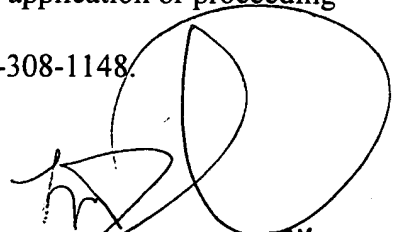
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on 703-308-0994. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9302 for regular communications and 703-872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1148.

KS

KS

September 6, 2002


LINDA C. M. DVORAK
SUPERVISORY PATENT EXAMINER
GROUP 3700